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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,365	08/05/2003	Clifford A. Wright	788114-1	8903
33651	7590	11/17/2004	EXAMINER	
JERRY RICHARD POTTS 3248 VIA RIBERA ESCONDIDO, CA 92029			PATEL, MITAL B	
		ART UNIT	PAPER NUMBER	
		3743		

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/634,365	WRIGHT, CLIFFORD A.	
	Examiner Mital B. Patel	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 June 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-25 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 16-20 is/are allowed.
- 6) Claim(s) 2-15 and 21-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10 June 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment/Arguments***

1. In response to Applicant's remarks with respect to providing a new Abstract that contains 150 words, it should be noted that a copy of new Abstract has not been provided as stated by Applicant. Please provide a copy of the new Abstract in response to the Final Office Action.
2. In response to Applicant's statement with respect to newly submitted claim 21, it should be noted that subject matter which the Examiner indicated would be allowed has not been incorporated into claim 21, specifically a recitation of a stop disposed at a distal end. Please note that the recitation of the extension tube being blocked at a distal end is not equivalent to a stop. Furthermore, the Examiner indicated the overall combination of a nasal cannula system that would include all the limitations of the base claim as well as the dependent claim would make the claim allowable. Applicant has not incorporated the base claim limitations and as such the Examiner disagrees with Applicant's contention that claim 21 should be allowable as well.
3. Applicant's arguments with respect to claim 21 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Gupta (US 2003/0111081 A1).

6. **As to claim 21**, Gupta teaches a nasal cannula system **200** comprising a nasal cannula (**formed by 210 and 212**) coupled between a pair of extension tubes **202,208**, wherein one of said extension tubes is blocked at a distal end thereof (**it should be noted that the distal end of tube 202 is blocked at 222 with 226 since oxygen is prevented from flowing through the tube to be inhaled by the patient; furthermore, Gupta discloses that clip 36 may be used at any portion along either of the tubes; See Col. 2**) and wherein the other one **208** of the extension tubes is adapted to be coupled (**at 224, 204**) to a fluid supply.

#### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3743

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 22-25 and 2-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta (US 2003/0111081 A1) in view of Bartholomew (US 5,400,776).

10. **As to claim 22**, Gupta teaches essentially all of the limitations except for means for supporting said cannula and portions of said pair of extension tubes from the ears of a user. However, Bartholomew does teach a nasal cannula system with a means **11** for supporting the nasal cannula and portions of said pair of extension tubes from the ears of the user in order to provide a longitudinal bend in the portion of the extension tube that fits behind each of the patient's ears (it should be noted that Gupta does teach extension tubes having portions that fit behind the patient's ears) in order to reduce discomfort. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the nasal cannula system of Gupta to include the means **11** of Bartholomew in order to provide a longitudinal bend in the portion of the extension tube that fits behind each of the patient's ears so as to reduce discomfort.

11. **As to claim 23,** the above combination teaches a system wherein said means for supporting includes an ear piece **39** having a recessed channel (**See Figs. 3, 4, and 6 of Bartholomew**) for receiving therein a portion of one of said extension tubes.

12. **As to claim 24,** the above combination teaches a system wherein said means for supporting further includes another ear piece having another recessed channel for receiving therein another portion of another one of said extension tubes (**See Fig. 2 of Bartholomew which depicts two ear pieces 39 for both ears**).

13. **As to claim 25,** Gupta teaches essentially all of the limitations except for a securing arrangement attached to either one of said pair of extension tubes for helping to holding the corresponding extension tube in a fixed position. However, Bartholomew does teach a securing arrangement **13**. It should be noted that Bartholomew does not explicitly teach the securing clip mounted to one of extension tubes. However, Bartholomew does teach that the securing clip is used to retain the cannula system to a patient's clothing to reduce patient discomfort. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the securing clip of Bartholomew on one of the pair of extension tubes of Gupta rather than on the fluid delivery tube as explicitly taught by Bartholomew so as to provide greater patient comfort, i.e., it would have been obvious to one of ordinary skill in the art to provide the securing clip anywhere on the cannula system to attach the cannula to the patient's body/clothing so as to achieve the greatest comfort.

14. **As to claim 2,** the above combination teaches a system, wherein said nasal cannula includes a pair of spaced apart nasal tips **210,212** of sufficient length for insertion into the nostrils of the user.

15. **As to claim 3,** the above combination teaches a system, wherein said pair of spaced apart nasal tips have substantially smaller outer diameter than said nasal delivery tube (**See Fig. 4 which shows nasal tips 210,212 to be smaller in diameter than tubes 202,208**).

16. **As to claim 4,** the above combination teaches a system, wherein said pair of spaced apart nasal tips **210,212** are trimmable to custom fit the user (**It should be noted that although the above combination does not explicitly disclose nasal tips which are trimmable, the nasal tips of the above combination are fully capable of performing the function or are able to be trimmed because it is well known in the art that the nasal tips are made of a flexible material which material would allow for the tips to be trimmed**).

17. **As to claim 5,** the above combination teaches a system, wherein each individual one of said ear pieces has disposed on its proximal end a guide **43** for helping to facilitate guiding an individual one of said pair of extension tubes into a corresponding one of said recessed tube channels and to facilitate securing slidingly said individual one of said pair of extension tubes to said ear piece.

18. **As to claim 6,** the above combination teaches a system, wherein said nasal delivery tube includes a pair of spaced apart nasal tips **210,212** of sufficient length for

insertion into the nostrils of a user.

19. **As to claim 7,** the above combination teaches a system, wherein said pair of spaced apart nasal tips have substantially smaller outer diameter than said nasal delivery tube (**See Fig. 4 which shows nasal tips 210,212 to be smaller in diameter than tubes 202,208).**

20. **As to claim 8,** the above combination teaches a system, wherein said pair of spaced apart nasal tips **210,212** are trimmable to custom fit the nostril depths of the user (**It should be noted that although the above combination does not explicitly disclose nasal tips which are trimmable, the nasal tips of the above combination are fully capable of performing the function or are able to be trimmed because it is well known in the art that the nasal tips are made of a flexible material which material would allow for the tips to be trimmed).**

21. **As to claim 9,** the above combination teaches a system, wherein each individual one of said ear piece recessed tube channels is sufficiently long to capture an individual one of said pair of extension tubes at two capture points **49, 51** (of Bartholomew ) and is sufficiently narrow at about a distal end thereof to fixedly secure (**See Col. 3, lines 18-20**) said individual one of said pair of extension tubes within said channel at one of the two capture points to help facilitate supporting said nasal cannula substantially below the nose of the user and in close proximity to the nostrils of the user.

22. **As to claim 10,** the above combination teaches a system, further comprising: a section of fluid delivery tubing **220** coupled to said at a distal end of the other one of said pair of slider extension tubes and having a fluid source connector **224,204**

disposed at its distal end to help facilitate the delivery of fluids to the lungs of the user.

23. **As to claim 11,** the above combination teaches a system, further comprising: a securing clip **13** mounted to said section of fluid delivery tubing to help secure the fluid delivery tubing in a fixed position relative to the user (**See also claim 25 rejection above**).

24. **As to claim 14,** the above combination teaches a system, wherein said fluid source is a source of oxygen (**See Fig. 4**).

25. **As to claim 12,** the above combination teaches essentially all of the limitations except for wherein the securing clip is mounted to the other one of said pair of slider extension tubes to help secure the other one of said pair of slider extension tubes in a fixed position relative to the user. It should be noted that Bartholomew does teach a securing clip **13**, however, Bartholomew does not explicitly teach the securing clip mounted to one of extension tubes. However, Bartholomew does teach that the securing clip is used to retain the cannula system to a patient's clothing to reduce patient discomfort. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the securing clip of Bartholomew on one of the pair of extension tubes of Gupta rather than on the fluid delivery tube as explicitly taught by Bartholomew so as to provide greater patient comfort, i.e., it would have been obvious to one of ordinary skill in the art to provide the securing clip anywhere on the cannula system to attach the cannula to the patient's body/clothing so as to achieve the greatest comfort.

26. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta (US 2003/0111081 A1) in view of Bartholomew (US 5,400,776) and further in view of Tiep et al (US 4,535,767).

27. **As to claim 13,** the above combination of Gupta/Bartholomew teaches essentially all of the limitations except for wherein said fluid source is a source of air. However, Tiep does teach a cannula system in which Tiep discloses in Col. 1, lines 9-12, that "Virtually everyone is aware of the fact that it is frequently necessary or advisable to deliver oxygen enriched air or other gases or gas mixtures to patients during various different types of therapy." Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a source of air as the fluid source in the system of Gupta/Bartholomew as taught by Tiep depending on the type of therapy the patient is receiving.

28. **As to claim 15,** the above combination of Gupta/Bartholomew teaches essentially all of the limitations except for wherein said fluid source is a gas mixture source to help facilitate user breathing. However, Tiep does teach a cannula system in which Tiep discloses in Col. 1, lines 9-12, that "Virtually everyone is aware of the fact that it is frequently necessary or advisable to deliver oxygen enriched air or other gases or gas mixtures to patients during various different types of therapy." Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a gas mixture source as the fluid source in the system of Gupta/Bartholomew as taught by Tiep depending on the type of therapy the patient is receiving.

***Allowable Subject Matter***

29. Claims 16-20 are allowed over the prior art of record.
30. The following is a statement of reasons for the indication of allowable subject matter: As to claims 16-18, the prior art of record does not teach nor render obvious the overall claimed combination of a method of delivery fluid to a user specifically comprising the step of placing a stop at a distal end of one of the pair of slider extension tubes and wherein the other one of the pair of slider extension tubes has a distal end adapted to be coupled to a fluid source. As to claim 19, the prior art of record does not teach nor render obvious the overall claimed combination of an oxygen delivery system having a pair of extension tubes plugged at a distal end thereof with a stop and is adapted to be coupled at a proximate end thereof to a supply of air and a pair of ear pieces with recessed channels and the pair of extension tubes cooperating with the pair of ear pieces to facilitate positioning the pair of extension tubes within the respective ones of the recessed channels to support the nasal cannula from the ears of the user with the nasal prongs inserted into the nasal cavities of the user. As to claim 20, the prior art of record does not teach nor render obvious the overall claimed combination of a cannula system wherein a stop is disposed at a distal end of one of the pair of slider extension tubes and wherein the other one of the pair of slider extension tubes has a distal end adapted to be coupled to a fluid source.

***Conclusion***

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6679265, US 6655385, US 6439234, and US 4602644.
32. If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.
33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

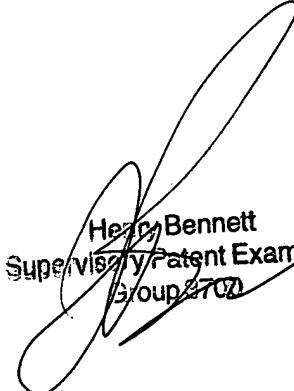
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Examiner  
Art Unit 3743

mbp



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